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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/949,904	10/15/1997	EDWARD R. LAVALLIE	GI-5288B	8744

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/21/2002

83

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/949,904

Applicant(s)
LaVallie et al

Examiner
Ungar

Art Unit
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 26, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-20, 22, 23, and 29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 22, 23, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 32
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. The Amendment filed August 26, 2002 (Paper No. 32) in response to the Office Action of March 26, 2002 (Paper No. 28) is acknowledged and has been entered. Previously pending claims 25 has been canceled, claim 20 has been amended. Claims 18-20, 22, 23, and 29 currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are maintained:

Double Patenting

4. Claims 18-20, 22, 23, 29 remain rejected under the judicially created doctrine of double patenting for the reasons previously set forth. This rejection will be held in abeyance until such time as either USSN 08/848,439 or the instant application is found allowable.

Claim Rejections - 35 USC § 101

5. Claims 18-20, 22, 23, and 29 remain rejected under 35 USC 101 for the reasons previously set forth in Paper No. 28, Section 8, pages 4-11.

Examiner apologizes for the inadvertent typographical error wherein claims 1-8, not pending in the current application, were rejected. Applicant appropriately realized, from the content of the rejection, that the rejection was drawn to then pending claims 18-20, 22, 23, 25 and 29 and clearly in the interests of compact prosecution, treated the rejection as pertaining to all of the pending claims.

Applicant argues that (a) the claimed invention is supported by a substantial, well-established and credible utility and cites Example 7 and p. 4, lines 24-31, (b) Applicant further submits Attachment A drawn to SFRP-2 which applicant suggests

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is SDF-5 which Applicant states is indicative of the ability of human SDF-5 protein to regulate the binding of Wnt proteins, (c) in view of the evidence presented, Applicant states that the encoded protein of SEQ ID NO;2/3 **may** (emphasis added) be capable of binding the Wnt proteins and thus capable of regulating the binding interaction of Wnt gene products to receptor proteins.

The arguments have been considered but have not been found persuasive because (a') page 4, lines 24-31 discloses human SDF-5 having amino acid sequence of SEQ ID NO;2 as well as homologues found in other species. It is not clear how this statement provides support for the utility of the claimed invention for the reasons previously set forth. Further, Example 7 demonstrates the localization of SDF-5 mRNA in sections of mouse embryo wherein the mRNA was expressed in developing joints of appendicular skeleton and some tendons and ligaments, no expression was detected in the bones of the axial or appendicular skeleton.

Applicant argues that based on the hybridization results it was considered likely that cartilage formation would be regulated by SDF-5. However, Applicant does not discuss the findings of Shirozu et al of record specifically teach that murine SDF-5 mRNA is expressed in brain, heart, kidney, lung and thymus. It is clear, given the widely distributed expression of murine SDF-5 mRNA that it can neither be predicted nor determined that SDF-5 regulates cartilage formation and that additional experimentation is required in order to determine a real world use for the claimed invention and that the invention does not have substantial utility. Since additional work must be done in order to establish a real world use for the claimed invention, it does not have a well-established utility. Example 7 also demonstrates that murine SDF-5 (produced by transfection of the isolated cDNA) alone had no

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effect *in vitro* on cells of bone or cartilage phenotype but when combined with BMP-2, *in vitro*, cartilage markers were reduced or absent, similar to another polypeptide in combination with BMP-2. Applicant argues that the decrease in bone and hypertrophic cartilage markers and the concomitant enhancement of cartilage phenotypes with the SDF-5/BMP-2 combination indicates that SDF-5 blocks the transition of differentiating chondrocytes into osteoblasts and at the same time shifts the cells to become chondrocytes. This implies that SDF-5 is blocking Wnt activity and that both BMP-2 and Wnt(s) are required for osteoblast differentiation. This argument is not persuasive because although Applicant suggests that the data “implies that SDF-5 is blocking Wnt activity”, no one would believe it more likely than not that SDF-5 blocks Wnt activity because as previously disclosed, the putative protein lacks the consensus sequence of the Wnt binding domain.

Although SDF-5 appears to have an additive effect with BMP-2 in an *in vitro* environment, the meaning of this information is unclear. It cannot be determined from the information in the specification whether SDF-5 in combination with BMP-2 indeed blocks the transition of differentiating chondrocytes into osteoblasts or shifts the cells to become chondrocytes. Additional work is required to determine if this effect occurs *in vivo* and how to use this information and additional experimentation must be done. Therefore the claimed polypeptide does not have substantial utility. Since additional work must be done in order to establish a real world use for the claimed invention, it does not have a well-established utility. Given the information in the specification and what is known in the art, no one would believe it more likely than not that the claimed invention has utility in chondrocyte or cartilaginous tissue maintenance and/or formation, (b’) the submitted

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Attachment cannot be evaluated as no nexus has been demonstrated between SDF-5 and sFRP-2 and no Declaration under 37 CFR 132 has been submitted. 37 CFR 132 reads in pertinent part:

When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.

(c') it is clear from Applicant's statement that further experimentation is required to determine how to use the claimed invention. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

6. Claim 20 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 28, Section 5, pages 2-3 and in Paper No. 12, Section 4, pages 2-4, Paper No. 8, Section 3, pages 3-5.

Applicant argues that for the reasons set forth above, the specification is enabling for *in vivo* treatment of related diseases or conditions. The arguments have been considered but have not been found persuasive for the reasons set forth above and for the reasons set forth previously in paper No. 12, Section 4, pages 2-4. It is noted that Applicant has not addressed the issues raised drawn to the extrapolation of *in vitro*, cell culture experiments to support the use of therapeutic compositions, the teachings of Freshney or record, the teachings of Dermer of record. Applicant's arguments have not been found persuasive and the rejection is maintained.

7. Claims 18-20, 22, 23, and 29 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 28, Section pages 11-19.

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Applicant argues that this rejection parallels the rejection under 35 USC 101 and for the reasons discussed above, the claims are enabled. The argument has been considered but has not been found persuasive for the reasons set forth previously and above. Further, the arguments set forth above were drawn to the utility of the claimed invention. Even were the utility of the claimed invention to be established, the invention would still not be enabled because, for the reasons set forth previously and above, one would not know how to use the claimed invention. Applicant's arguments have not been found persuasive and the rejection is maintained.

8. All other objections and rejections recited in Paper No. 28 are withdrawn.
9. No claims allowed.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

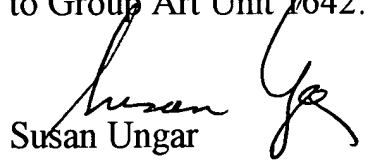
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(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
October 15, 2002